

REMARKS/ARGUMENTS

Claims 1-61 are pending. Citations to the Specification are directed to U.S. Patent Application No. 2007/0100143 (Reddy).

Favorable reconsideration is respectfully requested in view of the following remarks.

Rejection under 35 USC 112, second paragraph

Claims 16, 34-46 and 51-61 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

The Examiner argues that claim 16 recites the term "anti-solvent" has indefinite metes and bounds because there is no definition for said term in the specification, and alleges that it is unclear if this is another reagent, or a device, or a process.

In Hybri tech Inc. v. Monoclonal Antibodies, Inc., 231 USPQ. 81, 94 (CAFC 1986) it was stated:

". . . if the claims read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." (citing Shatterproof Glass Corp. v. Libbey Owens Ford. Co. 225 USPQ 634, 641 (CAFC 1985)).

Thus, whether a claim is in compliance with the second paragraph of § 112 requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.

Here, the Specification discloses with regard to the term "anti-solvent" that (¶[0011]):

Crystallization may be initiated by a method usually known in the art such as cooling, seeding, partial removal of the solvent from the solution, by adding an anti-solvent to the solution or a combination thereof.

Additionally, the Specification discloses with regard to the term "anti-solvent" that (¶[0015]):

Forcible crystallization may be initiated by a method usually known in the art such as cooling, seeding, partial removal of the solvent from the solution, by adding an anti-solvent to the solution or a combination thereof.

Therefore, it is clear from the Specification that the anti-solvent is added to initiate or force crystallization of a solute from a solution. Accordingly, one skilled in the art would understand what is claimed when the claim is read in light of the specification.

The Examiner argues that claim 34 and claims dependent thereon recite the limitation of "activated tetrahydro-2-furoic acid" which is not clear how it differs from the usual tetrahydro-2-furoic acid.

However, here the Specification discloses that (¶[0020]):

Activated tetrahydro-2-furoic acid refers to tetrahydro-2-furoic acid having its carboxylic acid group in a conventional activated form.

Thus, one skilled in the art would understand what is claimed when the claim is read in light of the specification.

In view of the case law cited above, the claims as presently before the Examiner and the above explanations and/or arguments, it is respectfully submitted that the claims presently pending in this application comply in all respects with the requirements of 35 U.S.C. § 112, second paragraph and reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 USC § 102

Claims 1-8, 12-19, 21, 23, 34-36, 39, 41, 43, 45, 46 and 48-50 stand rejected under 35 U.S.C. 102(b) as being anticipated by Manoury (U.S. Patent No. 4,315,007). This rejection is respectfully traversed. The Examiner argues that alfuzosin base is described in Example II at the step of adding chloroform and sodium hydroxide, then dried over magnesium sulfate and evaporated under vacuum (see column 3, lines 67-68 and column 4, lines 1-2).

In Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP 2131), the CAFC set forth that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". In the instant case, not every element of the claims is present in the '007 patent.

The claims are directed to crystalline alfuzosin base, and processes for the preparation of crystalline alfuzosin base. However, the '007 patent discloses ('007, column 3, line 66 to column 4, line 2):

After stirring the aqueous layer is decanted. The residual oil is taken up in chloroform, the organic solution is washed with 2-N sodium hydroxide, dried over magnesium sulfate and evaporated under vacuum.

This does not teach the production of a crystalline alfuzosin base, and is not a crystallization step. The claimed process for the preparation of crystalline solid of alfuzosin base is not disclosed in the prior art. The step in the method of the '007 patent referring to crystallization is directed to crystallization of alfuzosin hydrochloride ('007, column 4, lines 3-11):

The residual amine is transformed into the hydrochloride in 2-propanol by addition of the theoretical amount of ethanolic hydrogen chloride. One obtains 1.84 g of the hydrochloride of N₁-(4-amino-6,7-dimethoxyquinazol-2-yl)-N₁-methyl-N₂-(tetrahydrofuroyl-2)-propylenediamine melting at 235°C. A mixed melting point test confirms identity with the product of Example 1.

The disclosure in the '007 patent of crystallization in Example 1, cited by the Examiner, refers to the crystallization of the hydrochloride salt, not the base ('007, column 3, lines 21-25):

This yields a precipitate which is combined with the first and the whole is crystallized from a mixture of ethanol and ether. N₁-(4-Amino-6,7-dimethoxyquinazol-2-yl)-N₁-methyl-N₂-(tetrahydrofuroyl-2)-propylenediamine hydrochloride, which melts at 235°C (decomposition), is thus obtained.

Since the instant claims are directed to a crystalline form of alfuzosin base and processes for the preparation of crystalline alfuzosin base, which are not disclosed in the '007, the claims are not anticipated.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-8, 12-19, 21, 23, 34-36, 39, 41, 43, 45, 46 and 48-50 under 35 USC 102(b) is respectfully requested.

Rejection under 35 USC § 103

Claims 9-11, 20, 22, 24-33, 37, 38, 40, 42, 44 and 51-61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Manoury (U.S. Patent No. 4,315,007). This rejection is respectfully traversed.

The Examiner argues that the claims recite a process of crystallizing alfuzosin by using

solvents such as methyl-isobutyl ketone, methanol, ethanol, or acetone, and admits that these are not disclosed in Example I or II of Manoury. However, the Examiner argues that these solvents are within the same family as acetone, and isoamyl alcohol, or 2-propanol. The Examiner argues that it would have been obvious to develop the claimed process because it would have been within the level of the skilled chemist in this art to substitute one ketone or alcohol for another in the same family of alcohols for optimum yield, because it would have been optimization within prior art conditions or through routine experimentation.

However, the claims are patentable over the '007 patent for the following reasons. The framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows: (A) Determining the scope and content of the prior art; and (B) Ascertaining the differences between the claimed invention and the prior art; and (C) Resolving the level of ordinary skill in the pertinent art. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970). MPEP 2143.03. It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. (KSR v. Teleflex, 12 S.Ct. 1727, 1740 (US 2007)).

Here, not every element of the claims is taught or suggested in the '007 patent. The instant claims are directed to a process of crystallizing alfuzosin by using solvents such as methyl-isobutyl ketone, methanol, ethanol, or acetone. However, the prior art relied upon by the Examiner does not teach or suggest a process of crystallizing alfuzosin base, and further does not teach or suggest a process of crystallizing alfuzosin base by using solvents such as methyl-isobutyl ketone, methanol, ethanol, or acetone, as in the instant claims.

Furthermore, there is no motivation for one of skill in the art to alter the methods of the '007 patent to arrive at the claimed a process of crystallizing alfuzosin base, and no reasonable expectation of success. The Examiner argues that it would have been obvious to develop the claimed process because it would have been within the level of the skilled chemist in this art to

substitute one ketone or alcohol for another in the same family of alcohols for optimum yield, because it would have been optimization within prior art conditions or through routine experimentation.

However, it would not have been routine experimentation, because the cited reference does not teach or suggest a process of crystallizing alfuzosin base. In addition, the '007 patent does not disclose or suggest methods of preparation of crystalline alfuzosin base wherein the solvent is methyl-isobutyl ketone, methanol, ethanol, or acetone. Since the reference does not disclose or suggest this, there is no motivation to employ the process taught by the '007 patent to crystallize alfuzosin base and expect to obtain the desired product to reach the limitations of the claims, and no expectation of success.

Since, the '007 patent does not teach or suggest all the claim limitations, specifically the '007 patent does not teach or suggest a process of crystallizing alfuzosin base, and further does not teach or suggest methods of preparation of crystalline alfuzosin base wherein the solvent is methyl-isobutyl ketone, methanol, ethanol, or acetone, and therefore, since the '007 patent does not disclose or suggest these limitations, there is no motivation to alter the reference to reach these limitations, and no expectation of success.

Accordingly, reconsideration and withdrawal of the rejection of claims 9-11, 20, 22, 24-33, 37, 38, 40, 42, 44 and 51-61 under 35 USC 103(a) is respectfully requested.

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For at least the reasons set forth above, it is respectfully submitted that the above-

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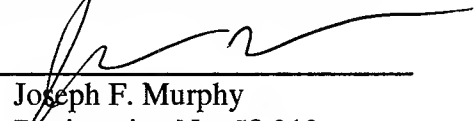
identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

By


Joseph F. Murphy
Registration No. 58,313
Customer No. 03000
(215) 567-2010
Attorneys for Applicants

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